REMARKS

Receipt of the Office Action mailed April 15, 2009 is hereby acknowledged. Reconsideration of the rejections in view of the foregoing amendments and the following remarks is respectfully requested.

Amendments

Claims 1-57 have been cancelled and replaced with new claims 58-70. New independent claim 58 is supported in the specification at page 7, lines 24-30, page 12, lines 18-22, page 13, line 26, original claim 40. Claims 61-62 are supported in the specification at page 7, lines 30-31. Claims 63-68 are supported in the specification at page 17, line 25 - page 18, line 17, and page 22, line 30 - page 23, line 15. Claims 69-70 are supported in the specification at page 13, lines 15-32.

Rejections under 35 U.S.C. § 112

The Examiner rejected claims 20-21, and 24-31 under 35 U.S.C. § 112, second paragraph, on the grounds that the claims were allegedly indefinite. Applicant has cancelled those claims, obviating the rejections. Applicant notes that in the

new claims, the word "about" has been omitted to avoid any potential § 112 issues.

Rejections over Dudrick

The Examiner has rejected claims 19, 22–26, 28-29, and 32 under 35 U.S.C. § 102(b) as allegedly anticipated by Dudrick, et al., U.S. Patent No. 5,026,721 ("Dudrick"). Applicant respectfully traverses this rejection. Claim 57 recites that the LNAA supplement contains the following amino acids: Tyr, Trp, Met, iLeu, Thr, Val and Leu, Lys, and optionally basic amino acids selected from Arg and His, as the sole amino acid ingredients. Thus, no other amino acids may be present in the presently claimed compositions. Dudrick, by contrast, requires the presence of Glu in its formulations (see, col. 2, lines 47-49, and Table I and II, and claim 1). Since Glu in not present in Applicant's formulations, Dudrick cannot anticipate the presently pending claims, requiring withdrawal of the rejections under § 102(b).

Rejections over Wachtel

The Examiner has rejected claims 17-33, 35-36, and 56 under 35 U.S.C. § 103(a) as allegedly unpatentable over Wachtel, et al., DE 4037447 ("Wachtel").

The Examiner appears to have accepted Applicant's position, supported by the Rule 132 Declaration of Jan Ruud Hansen, that Wachtel did not anticipate the claims, because the ranges Wachtel recited fell outside the scope of Applicant's claims. However, the Examiner has now imposed an obviousness rejection over Wachtel on the grounds that the word "about" "is considered to include values up to 4 times those claims, which would mean that the 65mg taught by Wachtel et al are "about 30mg"" (Office Action, pp. 6-7). Applicant traverses.

The Examiner has not provided any justification for her assertion that the term "about" introduces a variance in a stated value of up to 4 times. And, there is no basis for such a conclusion. It is not understood where such an understanding comes from. Moreover, Applicant submits that a person of ordinary skill in the art would not understand a claim term "about 30mg" (for example) to include a value of 65mg, which is more than 2 times the value of 30mg. In any event, the new claims do not include the term "about." Therefore, it is

undisputed that the presently pending claims are novel over the disclosures of Wachtel.

With respect to the obviousness rejection, Wachtel relates to a phenylalanine-free diet based on amino acids for persons afflicted with phenylketonuria (PKU), especially for juveniles and adults, characterized in that the amino acid residues constitute at least 95 % of His, Ile, Val, Thr, Met, Leu, Trp, Tyr and Lys. It appears from Wachtel's specification that in order to attain normal mental and physical growth for a child suffering from PKU, its Phe level in the plasma must be reduced to normal values *with a Phe poor diet*, and the Phe level must be stabilized (Wachtel, p. 5). Children are given a diet that contains a restricted quantity of natural protein and as much Phe as is required by the body for building up protein. Only foodstuffs that have low protein content by nature and thus low content of Phe can be used. Id. Therefore, children suffering from PKU and being on a Phe poor diet will require in addition to the Phe poor diet a protein source which does not contain Phe but sufficient quantity of all other amino acids.

Experts advise the patients to maintain Phe poor diet for life. Before the disclosures of Wachtel, it was believed that protein metabolism required the simultaneous presence of

all and even the non-essential amino acids. Therefore, the most commonly used products or Phe-free amino acid mixtures for babies and children contained all amino acids with the exception of Phe. A considerable amount of such a substance must be taken by the patient to cover the daily need of the patient. By adolescence, however, the treatment requirements of PKU were often refused by the patient (Wachtel, p. 6).

Wachtel, therefore, sought to prepare a Phe free diet or a Phe free amino acid mixture, which is more readily accepted by patients suffering from PKU and "conforms to the requirements of life-long intake of diet" (Wachtel, p. 7). Wachtel's solution was to cover completely (or almost completely) the daily protein requirement of juveniles and adults suffering from PKU with an amino acid mixture which contains predominantly or exclusively essential amino acids with the exception of Phe, Tyr and His (Wachtel, p. 8). Wachtel further discloses that if patients suffering from PKU use the Wachtel diet, they would only need to consume half the daily dosage when compared to the prior art amino acid mixtures, leading to better patient compliance with the diet (Wachtel, p. 9).

The present invention is quite different. This is explained in the specification, beginning at page 28, line 18. The problem is to provide an alternative and improved PKU treatment compared to the usual treatment. As stated earlier, Wachtel seeks to provide a Phe poor diet with optimal nutritional make-up and optimal acceptance by the patient in a life-long diet, where, by contrast, the present invention relates to alternative and improved LNAA compositions with improved efficiency in the treatment of PKU patients.

Wachtel does not in any way suggest modifying the Wachtel mixture in order to obtain a *better* - in the meaning of being therapeutically more effective - composition for the treatment of PKU. The Examiner's mere assertion that it would be "routine experimentation" to do so is not supported by any evidence. As such, Applicant submits that the § 103(a) rejection over Wachtel should be withdrawn.

Conclusion

Applicant believes the currently pending claims are now in condition for allowance. If the Examiner has any questions regarding this response, the Examiner is invited to telephone Applicant's counsel at the number provided below.

Respectfully submitted,
JACOBSON HOLMAN PLLC

By _____
Harvey Jacobson, Jr.
Reg. No. 20,851

400 Seventh St., N.W.
Washington, D.C. 20004
(202) 638-6666